



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103792/5004

DEC 11 2001

Robert L. Garnick, Ph.D.
Genentech Incorporated
1 DNA Way, MS #48
South San Francisco, CA 94080

Dear Dr. Garnick:

Your request to supplement your biologics license application for Trastuzumab to revise the package insert to include updated median survival data has been approved.

Please submit all **final** printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

A handwritten signature in cursive script that reads "Patricia Keegan for Dr. Weiss".

Karen D. Weiss, M.D.
Director
Division of Clinical Trial Design
and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research